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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,711	04/18/2006	Kunio Ishikawa	TSUZ 2 00026	8622
27885	7590	07/20/2009		
Fay Sharpe LLP 1228 Euclid Avenue, 5th Floor The Halle Building Cleveland, OH 44115			EXAMINER	COTRONEO, STEVEN J
ART UNIT	PAPER NUMBER	3733		
MAIL DATE		DELIVERY MODE		
07/20/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,711	<b>Applicant(s)</b> ISHIKAWA ET AL.
	<b>Examiner</b> STEVEN J. COTRONEO	<b>Art Unit</b> 3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 25 March 2009.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-9 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 25 March 2009 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-166/08)  
 Paper No(s)/Mail Date 3/31/2009

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

### **DETAILED ACTION**

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Constantz (US Patent 5,952,010).

Constantz discloses a method of producing a bone substitutes material composed of carbonate apatite formed by contacting a foam block of calcium compound containing a calcium carbonate mixture (col. 5 ll. 28-52 and col. 6 ll. 1-11) with a phosphate containing solution (col. 5 ll. 19-27). The calcium mixture ingredients are uniformly dispersed so that the material has substantially no powder (col. 5 ll. 3-5, "monophasic having a single crystal structure. As compared to sintered hydroxyapatite... the subject compositions are substantially different" Sintered HA is powdered causing the need for sintering). The material is allowed to anneal to a hardened integral mass (col. 6 ll.38-47) and is not sintered (col. 5 ll. 2-8). The carbonate content is .5% or more by weight ("2-10%" col. 6 ll. 48-52). The block will not have any powders (col. 7, ll. 48-50, "Clay or paste like mixture") The block is immersed in the phosphate solution (col. 9, ll. 4-10 "calcium carbonate combined (or immersed) with phosphoric acid and sodium phosphate").

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz (US Patent 5,952,010) in view of Hall (Hall, Brian. "Experimental investigation on Pore Size and Pore Distribution," Bone: Fracture Repair and Regeneration. Volume 5. 1991. CRC Press, Inc. pages 161-162. Accessed through Google books on 7/15/09. PDF of relevant pages provided.)

Constantz discloses the claimed invention except the pore diameter being in the range of 50-1000 $\mu$ m. Constantz does disclose that the compositions can be provided to best mimic natural calcified tissue in both form and function (col. 10, ll. 30-36).

Hall discloses the most appropriate pore size for bone implants to be between 50 and 400  $\mu$ m to allow for osteon formation.

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the device of Constantz with the pore diameter being in the range of 50-1000 $\mu$ m in view of Hall in order to mimic bone tissue and allow for osteon formation.

***Response to Arguments***

Applicant's arguments, see Remarks page 5, filed 3/25/2009, with respect to the objection to the drawings have been fully considered. The objection of the drawings has been withdrawn due to corrected drawings.

Applicant's arguments filed 3/25/2009 with respect to claims 1-6 have been fully considered but they are not persuasive. The applicant argues that the calcium in Constantz is not in the form of a block having no powder. The examiner respectively disagrees. A block according to Merriam-Webster is "a compact usu. solid piece of substantial material esp. when worked or altered to serve a particular purpose." The calcium is a piece of material and it is worked or altered to form the final composition of Constantz therefore the calcium source is a block.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN J. COTRONEO whose telephone number is (571)270-7388. The examiner can normally be reached on M-F 730-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. C./  
Examiner, Art Unit 3733

/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733